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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,695	09/25/2003	Wayne A. Jensen	DI-9-1	8741

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EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/670,695	JENSEN ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-54,58-60,62-71,75 and 82-107* is/are pending in the application.

4a) Of the above claim(s) *58,59,62,82,85,86 and 89* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-54,60,63-71,75,83,84,87,88 and 90-107* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/25/03,11/3/03,9/12/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Office acknowledges the receipt of Applicant's election and Amendment, filed on 30 March 2006. Claims 55-57, 61, 72-74, and 76-81 have been cancelled. New claims 82-107 have been added.

Election/Restrictions

Applicant elects Group I, claims 40-75, SEQ ID NO:22, and the species of herpes virus, with traverse.

The traversal is on the grounds that the SEQ ID NO's listed in the claims have been disclosed as capable of being used together and do not pose a search burden on the Examiner, and that the claimed method must make use of more than one antigen in order to determine the immune status to more than one virus. Applicant's traversal has been fully considered but is unpersuasive for the following reasons:

Applicants' contention of common utility to the sequences claimed in the application is improper because each nucleotide/amino acid sequence is not considered to be a proper member of a Markush group. See M.P.E.P. § 803.02. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

The instant claims are drawn to multiple oligonucleotides and peptides, which are considered to be unrelated, since each sequence claimed is structurally and functionally

independent and distinct due to the unique sequence. As such, the sequences in the instant claims are not considered to constitute a proper Markush group/genus, and are therefore subject to restriction. Furthermore, a search of more than one of the sequences present in these claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search in terms of computer time needed to perform the search and the subsequent analysis of the search results by the examiner. In view of the foregoing, one sequence is considered to be a reasonable number of sequences for examination.

The instant amino acid sequences for the feline herpesvirus antigen alone vary in length from 250 to 943 residues. The vast size difference in the primary structure contributes to differences in the secondary structures, i.e. alpha helices and beta sheets, the tertiary structure, and the quaternary structure of the protein folding. In other words, as already indicated in the prior Office Action, each SEQ ID NO represents a structurally different polypeptide encoded by a different polynucleotide, even though they all belong to the same protein family possessing the same general function. The length and the overall three-dimensional structure of the polypeptide determine the binding specificity and immunogenicity of each polypeptide. Therefore, each SEQ ID NO is a separate invention. Accordingly, applicants are required to elect one sequence.

However, SEQ ID NO: 18, 20, and 22 are examined together in light of the sequence alignment provided by Applicants.

Applicants' contention that the claimed method must make use of more than one antigen deviates from the limitations in the instant claims. The base claim 40 recites "an infectious agent" and nowhere recites multiple infectious agents.

It is noted that Applicant is no longer entitled to the rejoinder of the process claims with the product claims under *In re Ochiai* and *In re Brouwer* because Applicants have elected the process claims. See M.P.E.P. §821.04.

The restriction among the different methods is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Claims 40-54, 58-60, 62-71, 75, and 82-107 are pending. Claims 58, 59, 62, 82, 85, 86, and 89 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 30 March 2006.

Claims 40-54, 60, 63-71, 75, 83, 84, 87, 88, and 90-107 are examined in the instant application and read to the extent that they read on the elected sequences and species.

Information Disclosure Statement

An initialed and dated copy of each of Applicant's IDS form 1449, filed on 12 September 2005, 3 November 2003, and 25 September 2003, respectively, is attached to the instant Office action.

Specification

Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40, 65-68, 83, 84, 87, 88, 93-96, and 102-105 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The M.P.E.P. states that the purpose of the written description requirement is to ensure that the inventor had possession, at the time the invention was made, of the specific subject matter claimed. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant

> complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

M.P.E.P. § 2163 further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." M.P.E.P. § 2163 does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See M.P.E.P. § 2163. Although the M.P.E.P. does not define what constitutes a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*,

the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention*. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." M.P.E.P. §2163.

In the instant case, the claims are directed to a method to determine the immune status of an animal against an infectious agent, said method comprising the steps of: contacting a biological specimen of said animal with a recombinant antigen capable of forming a complex with an antibody specific for said infectious agent under conditions suitable for formation of said complex, wherein said recombinant antigen is a protein from said infectious agent, and wherein said protein is free of contaminants that result in false positives, and wherein said infectious agent is a feline herpesvirus; and (b) detecting the presence or absence of said complex, wherein the presence or absence of said complex is indicative of the immune status of said animal. These limitations encompass all mutated sequences, truncations, structural or functional homologs of the recombinant antigen, and so forth. Thus, the claims are drawn to a genus of nucleic acids or amino acids that is defined only by functional reduction.

The only factor present is a recombinant antigen, or more specifically, of the elected SEQ ID NO:22 amino acid sequence. There is no identification of any particular portion of the structure that must be conserved in the claimed "recombinant antigen." The specification only provides description for a number of proteins. Specifically, the claims contain the phrases "an amino acid," "a nucleic acid," and "at least about 85% identity with," which are not described in the specification in any manner. The specification only provides description for one antigen encoded by SEQ ID NO:22, which is used to detect antibodies against feline herpesvirus (FHV) in FHV-vaccinated cats (Example 4D, ¶ 96-103, p. 53-57, and Example 7, p.61-66).

As stated *supra*, the M.P.E.P. states that written description for a genus can be achieved by a representative number of species within a broad genus. Claims 40, 65-68, 83, 84, 87, 88, 93-96, and 102-105 are broadly generic to an enormous number of fragments or 85% homologs encompassed by the claims. The M.P.E.P. states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." M.P.E.P. § 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the recombinant antigen beyond those disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus since the specification

does not provide any examples of an amino acid of at least about 85% identity to SEQ ID NO:22.

As discussed above, the skilled artisan cannot envision the detailed chemical structure and function of the encompassed genus of undefined nucleotide and/or peptide fragments. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or synthesis. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of cloning or isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. Therefore, only the xxx has been described.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483, claims directed to mammalian FGF's were found to be unpatentable due to lack of written descriptions for that broad class. The specification provided only the bovine sequence.

While having written description of optimized FHV glycoprotein C of SEQ ID NO:22 identified in the specification tables and/or examples, the specification is devoid of any fragments, or homologs with at least about 85% identity, that qualify for the functional characteristics claimed. A definition by function alone "does not suffice, to sufficiently describe a coding sequence" because it is only an indication of what the gene does, rather than what it is." *Eli Lilly*, 119F.3 at 1568, 43USPQ2d at 1406.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

The patent law requires that a patent contain a written description of a claimed invention independent of the requirements to enable one skilled in the art to make and use the invention. See e.g., *Invitrogen Corp. v. Clontech Labs, Inc.*, 429 F.3d 1052, 1071 n.17 (Fed. Cir. 2005) ("written description is distinct from the enablement requirement"); *Capon v. Eshhar*, 418 F.3d 1349, 1360 (Fed. Cir. 2005) ("although the legal criteria of enablement and written description are related and are often met by the same disclosure, they serve discrete legal requirements").

Therefore, claims 40, 65-68, 83, 84, 87, 88, 93-96, and 102-105 do not meet the written description provision of 35 U.S.C. §112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variable. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (page 1115).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a), which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 40-54, 60, 69-71, 75, 90, 91, 97-100, 106, and 107 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hofmann-Lehmann *et al.* (1996, in IDS filed on 25 September 2003) in view of Prud'homme *et al.* (1997, in IDS filed on 25 September 2003).

The instant claims are drawn to a method to determine the immune status of an animal against an infectious agent, said method comprising the steps of: contacting a biological specimen of said animal with a recombinant antigen capable of forming a complex with an antibody specific for said infectious agent under conditions suitable for formation of said complex, wherein said recombinant antigen is a protein from a feline herpesvirus (FHV), and wherein said protein is free of contaminants that result in false positives; and (b) detecting the presence or absence of said complex, wherein the presence or absence of said complex is indicative of the immune status of said animal.

Hofmann-Lehmann *et al.* describes a method of determining the prevalence of antibodies to feline herpesvirus. A biological specimen of an animal was contacted with "crude antigens" obtained from a candidate virus in order to determine the presence or absence of antibodies to that virus. Specifically, Hofmann-Lehmann *et al.* describes

detection of antibodies to FHV in sera by enzyme-linked immunosorbent assay (ELISA) and by indirect immunofluorescence assay (IFA) (p. 556, left column, ¶3).

Hofmann-Lehmann *et al.* does not describe the same method as claimed because Hofmann-Lehmann *et al.* uses crude antigens instead of a recombinant antigen.

Prud'homme *et al.* discloses a competitive ELISA for detection of antibodies of pseudorabies virus, an alphaherpesvirus, in animal sera using a recombinant herpesvius glycoprotein antigen, gp50. See page 278, Materials and Methods.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to modify the crude antigen of the Hofmann-Lehmann method such that a recombinant antigen of the Prud'homme method is used for detection of antibody. One having ordinary skill in the art would have been motivated to substitute the crude antigen with a recombinant antigen as an alternative method of Hofmann-Lehmann in view of the advantages of the ease of the antigen production without the requirement of high biosafety level facilities and minimization of batch-to-batch variation, as suggested by Prud'homme *et al.* Thus, claims 40-54, 60, 69-71, 75, 90, 91, 97-100, 106, and 107 are obvious over Hofmann-Lehmann *et al.* in view of Prud'homme *et al.*

Claims 40-54, 60, 63-71, 75, 83, 84, 87, 88, and 90-107 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hofmann-Lehmann *et al.* (1996) in view of

Prud'homme *et al.* (1997), and further in view of Maeda *et al.* (1997, in IDS filed on 25 September 2003).

The instant invention is further limiting the antigen to a recombinant feline herpesvirus glycoprotein C protein.

Maeda *et al.* discloses the nucleotide and amino acid sequence of the FHV type 1 (FHV 1) glycoprotein C (gC) protein, which aligns with the instantly claimed SEQ ID NO:22, and thus, Maeda *et al.* also discloses all nucleotides and encoding proteins with at least about 85% identity to SEQ ID NO:18, 20 and 22. See page 107. Since the sequence is disclosed, Maeda *et al.* also suggests the synthesis of this protein recombinantly in COS cells. Maeda *et al.* further describes the detection of the recombinant FHV-1 gC by IFA and flow cytometry.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to use the antigen suggested by Maeda *et al.* rather than any herpesvirus antigen. One having ordinary skill in the art would have been motivated to use this specific recombinant antigen since Maeda *et al.* explicitly suggests the application of this protein as an important subunit antigen in vaccine immunity for FHV-1 infection in cats (p. 108, last ¶). Thus, claims 40-54, 60, 63-71, 75, 83, 84, 87, 88, and 90-107 are obvious over Hofmann-Lehmann *et al.* in view of Prud'homme *et al.*, and further in view of Maeda *et al.*

Remarks

No claim is allowable.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D., whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902.

Louise Humphrey, Ph.D.
Assistant Patent Examiner
28 April 2006

JEFFREY STUCKER
PRIMARY EXAMINER